JUN 2 4 2003

COLORADO 2™ Spinal System
510(k) Summary K030875
May 2003

I. **Company:** **Medtronic Sofamor Danek USA, Inc.**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name: COLORADO 2™ Spinal System**
Regulation Numbers: 888.3050, 888.3060 and 888.3070

Regulation Names: Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Body Fixation Orthosis, Spondylolisthesis Spinal Fixation Device System, and Pedicle Screw Spinal System.

Codes: MNH, MNI, KWP, KWQ

III. Product Description

The COLORADO 2™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. COLORADO 2 ™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. COLORADO 2™ Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2.

The COLORADO 2™ Spinal System can be connected to only 5.5mm rods of the TSRH® Spinal System, CD HORIZON® Spinal System, GDLH®, and the TENOR™ Spinal Systems through 5.5mm axial rod connectors (i.e., CD HORIZON® Domino, COLORADO 2™ Connector for Sacral and Illio-Sacral Plates, TSRH® Offset and Axial Plates, etc.). Components from other systems may not be combined with components of the COLORADO 2™ Spinal System. When used with the COLORADO 2™ Spinal System components, the components from the other systems may only be used for the COLORADO 2™ Spinal System indications.

IV. Indications

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the COLORADO 2™ Spinal System Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the COLORADO 2™ Spinal System is also indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the COLORADO 2™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used as an anterolateral thoracic/lumbar system, the COLORADO 2™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

V. Substantial Equivalence

The COLORADO 2™ Spinal System is substantially equivalent to other legally marketed devices and itself. A risk analysis was provided or referenced to demonstrate substantial equivalence.

The purpose of this submission was to add a 6.35mm rod along with associated connecting CD HORIZON® and TSRH® Spinal System components to the existing COLORADO 2™ Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

Richard W. Treharne, Ph.D.
Sr. Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132

Re: K030875
Trade/Device Name: COLORADO® 2 Spinal System
Regulation Number: 21 CFR 888.3050, 888.3060, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; Spinal intervetebral body fixation orthosis; Spondylolisthesis spinal fixation device-system; Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP, KWQ, MNH, MNI
Dated: June 11, 2003
Received: June 12, 2003

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUN 2 4 2003

510(k) Number (if known): K030875

Device Name: COLORADO 2™ Spinal System

Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the COLORADO 2™ Spinal System Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

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When used as a posterior, non-cervical, non-pedicle screw fixation system, the COLORADO 2™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.
When used as an anterolateral thoracic/lumbar system, the COLORADO 2™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use _____ OR **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N. Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030875